

510(k) SUMMARY

HSS PLAMP

#K942032

(prepared 4/3/96)

JUN 13 1996

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Trade Name(s): Plamp, plamp plate, plamp with hook
Common Name: Bone plate with clamps
Classification Name: Plate, Fixation, Bone (per 21 CFR 888.3030)

The device is intended to fix periprosthetic fractures of the proximal femur and the humerus in a stable position to allow healing. The plamp plate with trochanteric hook is intended to fix non-unions of the trochanter in a stable position to allow healing.

The plamp is a mechanical combination of a bone plate and a bone clamp. The clamps connect to the plate via the screws and the bone is held between the plate and the clamps. Both the plate and the clamps have small spikes to fix the components to the bone. For periprosthetic fractures, additional fixation is achieved through the use of cortical bone screws that pass through the plamp plate. It is substantially equivalent to components of the Dall-Miles Trochanteric Cable Grip System (Howmedica) and the Dall-Miles Broad Bone Plate (Howmedica).

The use of spikes and clamps to hold fractured bones was examined in an animal model comparing the strength of bones fixed using standard bone plates, intramedullary rods and a clamp-like device. This experiment showed that the *in vivo* performance of the clamp portion of the plamp was superior to the use of plates alone as measured by torsional strength at failure and energy to failure.